

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
25 August 2005 (25.08.2005)

PCT

(10) International Publication Number  
**WO 2005/077933 A1**

(51) International Patent Classification<sup>7</sup>: **C07D 401/04**,  
A61K 31/505 // (C07D 401/04, 239:00, 213:00)

(21) International Application Number:  
PCT/IN2004/000352

(22) International Filing Date:  
16 November 2004 (16.11.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
105/CHE/2004 11 February 2004 (11.02.2004) IN

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: NOVEL POLYMORPHIC FORM OF IMATINIB MESYLATE AND A PROCESS FOR ITS PREPARATION

(57) Abstract: This invention discloses a novel stable crystal form of imatinib mesylate, designated by us as  $\alpha_2$  Form, which is stable at room temperature and even at higher temperatures upto 120 °C and accelerated stress conditions and, freely soluble in water. This invention also discloses a pharmaceutical composition containing the novel stable  $\alpha_2$  form of Imatinib mesylate and other usually employed excipients, useful in the treatment of Chronic Myelogenous Leukemia (CML). This new  $\alpha_2$  Form of imatinib mesylate is prepared by slurring Imatinib base in isopropanol at room temperature followed by addition of methane sulfonic acid and maintaining 50-60 °C followed by filtration. This invention also discloses another process for the preparation of the novel, stable  $\alpha_2$  crystalline form of Imatinib Mesylate by the conversion of Imatinib mesylate  $\beta$ -polymorphic modification by suspending it in water and organic solvents, distilling off water azeotropically, cooling and filtering to obtain the  $\alpha_2$  crystal form.



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